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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/510,126

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Gerardo Perez-Camargo

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EXAMINER

BARHAM, BETHANY P

ART UNIT

PAPER NUMBER

1615

NOTIFICATION DATE

DELIVERY MODE

03/18/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No. 10/510,126	Applicant(s) PEREZ-CAMARGO ET AL.	
	Examiner Bethany Barham	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2007 and 02 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-55 and 58-71 is/are pending in the application.
- 4a) Of the above claim(s) 38-47 and 61-71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48-55 and 58-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Summary

Applicant is reminded that the office has not received IDS as of this date.

Receipt of Applicant's Response filed on 08/15/07 is acknowledged. Claims 38-54 and 57-71 are pending. Claims 38-47 and 61-71 are withdrawn. Claims 48-54 and 57-60 are rejected.

Due to Applicant's Claim amendments the 102 rejection and 103 rejections of record are hereby withdrawn. Applicant is also reminded that the office has not received an IDS as of this date.

MAINTAINED REJECTIONS

DOUBLE PATENTING

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 48-54 and 57-60 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 39-60 of U.S.

Patent No. 10/509,949. Although the conflicting claims are not identical, they are not patentably distinct from each other because they claim substantially identical nutritional management regimens with an intestinal mucosa function-promoter and also pancreatic function promoter and/or liver function promoter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

NEW REJECTION:

Claims 48-54 and 57-60 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 61-66 of U.S.

Patent No. 10/509,951. Although the conflicting claims are not identical, they are not patentably distinct from each other because they claim substantially identical nutritional management regimens with an intestinal mucosa function-promoter and also pancreatic function promoter and/or liver function promoter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

NEW REJECTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 48 is rejected under 35 U.S.C. 102(b) as being anticipated by JP
408038063 A ('063).

- '063 teaches a pet food composition with omega fatty acids, preferably fish oil (abstract).

Claim 48 is rejected under 35 U.S.C. 102(e) as being anticipated by US
2001/0051206 ('206).

- '206 teaches a pet food composition including omega fatty acids such as flaxseed and fish oil (abstract, Example 1 and Table 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 48-55 and 58-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,471,999 ('999) in view of JP 408038063 ('063) or US 2001/0051206 ('206).

The limitations of claims 48-53 are taught:

- '999 teach a pet milk powder as nutritional milk that results in reduced gastrointestinal intolerance (abstract). '999 teaches that the milk powder when administered in an effective amount with the nutritional composition reduces gastrointestinal intolerance and that it may further comprise one or more lipid source, protein source, vitamins and minerals, and teaches a specific aspect which comprises lactose (of micro-organism origin), lactase, taurine, arginine and choline (claims 1-9; col. 2, lines 9-lines 26).
- '999 teaches omega fatty acids such as soybean and rapeseed oil and in Examples 1-2 (col. 3, lines 15-20).

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- '999 teaches including an alkali in the milk-based powder, which slows the pH, drop in the gastrointestinal tract (col. 2, lines 53-55). '999 teaches that a protein source of whey protein and further supplemented with taurine and a probiotic micro-organism which beneficially effects the host by improving its intestinal microbial balance, such as lactic acid (col. 3, lines 25-40).
- '999 teaches chicory fibers, inulin, fructooligosaccharides with the probiotic micro-organism have a symbiotic relationship for promoting beneficial effects (col. 4, lines 9-14).
- '999 teaches that the amount of nutritional composition is to be fed to a mammal each day depends of factors such as age, type of mammal (dogs and cats), and other nutritional sources (col. 4, lines 25-36).
- Examples 1 and 2 teach mixing the milk powder, galactosidase (lactase amino), vitamins, minerals, and soybean oil, and adding water to provide nutritional supplement to dogs and puppies or cats.

The limitations of claims 54-55 and 58-60 are taught:

- '999 teaches that a protein source of whey protein and further supplemented with taurine and a probiotic micro-organism which beneficially effects the host by improving its intestinal microbial balance, such as lactic acid (col. 3, lines 25-40).
- '999 does not teach omega fatty acids derived from fish oil.
- '063 teaches a pet food composition with omega fatty acids, preferably fish oil (abstract).

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- '206 teaches a pet food composition including omega fatty acids such as flaxseed and fish oil (abstract, Example 1 and Table 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute a known omega-3-fatty acid of rapeseed oil ('999) for the fish oil of '063 and '206 in the pet food composition of '999. One of ordinary skill in the art would recognize that fish oil has a high content of omega-3-fatty acid, and that it is known to include fish oil in pet foods to treat diseases. One of ordinary skill in the art would be motivated to combine the teachings of '999 and '063 or '206 since both teach that fish oil included in a pet food composition has beneficial effects for decreasing inflammation and allergic response. All teach including omega-3-fatty acids in the pet food compositions provide nutritional and health benefit and it is within the purview of the skilled artisan to substitute one known omega fatty acid for another with a reasonable expectation of success.

Claims 48-55 and 58-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuchs et al., WO 02/15719 ('719).

The limitations of claims 48-51 and 54 are taught:

- '719 discloses a method of treatment which comprises administering an effective amount of the composition which contains a lipid source including omega-3 fatty acids and whey protein (both intestinal mucosa function promoters according to applicant) to improve, promote, maintain intestinal function and mucins a patient or companion animal (abstract, claims 1-2 and 14-20, pg. 6 lines 5-10; pg. 12

lines 3-21). Example 4 teaches a nutritional supplement comprising whey protein and probiotic bacteria. '719 teaches that the nature of whey protein and the fact that it is capable of being easily digested, the composition has a beneficial effect in patients with limited appetite due illness, surgery, chronic gastritis, etc (pg. 4, line 31-pg. 5, line 6), and that the addition of a probiotic micro-organism provides the advantage of restoring the natural balance of the intestinal flora following antibiotic therapy (pg. 6, lines 7-10).

- Whey protein is taught by applicant to be a fat transportation aid agent and carrier (instant spec pg. 10, 13-20).
- '719 also teaches including a prebiotic (claim 13, pg. 5, lines 27-30).
- '719 teaches omega-3-fatty acids of including the oils of rapeseed, canola, soy, hazelnut, etc (pg. 8, lines 15-24).

The limitations of claims 52-53 and 58-60 are taught:

- '719 teaches including taurine and vitamins (claim 12, pg. 5, lines 18-25; pg. 6, lines 27-29)
- '719 teaches a nutritional supplement comprising whey protein and omega-3 fatty acids (abstract, claims 1-2).
- '719 does not teach omega fatty acids derived from fish oil, but does teach a pet food composition comprising omega 3:6 fatty acid content ratio of about 5:1 to about 10:1 (abstract).
- '063 teaches a pet food composition with omega 3:6 fatty acids ration of 3:1 to 10:1 preferably 5:1 to 7.5:1, and preferably fish oil (abstract).

- '206 teaches a pet food composition including omega fatty acids such as flaxseed and fish oil with a ratio of 5:1 of omega 3:6 fatty acids (abstract, Example 1 and Table 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute a known omega-3-fatty acid of rapeseed oil ('719) for the fish oil of '063 and '206 in the pet food composition of '999. One of ordinary skill in the art would recognize that fish oil has a high content of omega-3-fatty acid, and that it is known to include fish oil in pet foods to treat diseases. One of ordinary skill in the art would be motivated to combine the teachings of '999 and '063 or '206 since both teach that fish oil included in a pet food composition in an amount of 5:1 ratio of omega 3:6 fatty acid has beneficial effects for decreasing inflammation and allergic response. All teach including omega fatty acids in a 5:1 ratio in the pet food compositions provide nutritional and health benefit and it is within the purview of the skilled artisan to substitute one known omega-3-fatty acid for another with a reasonable expectation of success (see cited as interest).

CITED AS INTEREST

US 7,084,175 B2 ('175) teaches that animal foods have long contained various oils as sources of omega-3-fatty acids. '175 teaches that various beneficial omega-3-fatty acids include flaxseed, canola (rapeseed), linseed, perilla and fish oils, etc are

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included in pet food in order to promote favorable effects on the animals (col. 1, lines 53-30).

Wikipedia search of "omega-3-fatty acid" and "rapeseed" teaches that the oils of Flax, Linseed, Rapeseed, Soybean, Hazelnut, etc all contain omega-3-fatty acids as do Fish oil. Wikipedia also teaches that "six times richer than most fish oils in w-3,[72] Flax (aka linseed) (*Linum usitatissimum*) and its oil are perhaps the most widely available botanical source of w-3. Flaxseed oil consists of ca. 55% ALA (alpha-linolenic acid). Flax, like chia, contains approximately three times as much w-3 as w-6" and that "Canola oil (or rapeseed oil) contains both omega-6 and omega-3 fatty acids in a ratio of 2:1 and is second only to flax oil in omega-3 fatty acid."

Response to Arguments

Applicant's arguments with respect to claims 48-55 and 58-60 have been considered but are moot in view of the new grounds of rejection necessitated by applicants' amendments.

Conclusions

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bethany Barham whose telephone number is (571)-272-6175. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bethany Barham
Art Unit 1615

/Michael P Woodward/

Supervisory Patent Examiner, Art

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